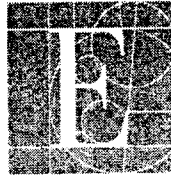


OCT - 2 2003



Edwards

510(k) Summary**1. Submitter's Name and Address:**

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614

2. Contact:

Kevin Drisko
Senior Manager, Regulatory Affairs
Edwards Lifesciences LLC
Phone: (949) 250-2416
Fax: (949) 250-3630
E-mail: kevin_drisko@edwards.com

3. Date Prepared:

August 21, 2003

4. Device Trade Name:

Edwards Peripheral Dilatation Catheter

5. Device Common Name:

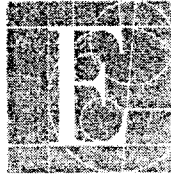
Peripheral dilatation catheter

6. Device Classification Name:

Catheter, percutaneous (DQY), Class II

7. Predicate Devices:

Cordis MAXI LD Esophageal Dilator (K023907)
Guidant AGILTRAC™ 035 Peripheral Dilatation Catheter (K023320)



Edwards

510(k) Summary (continued)

8. Device Description:

The Edwards Peripheral Dilatation Catheter is an over-the-wire-catheter with a flexible distal portion for maneuvering through regions of the peripheral vasculature. A balloon is mounted on the distal end of the catheter and provides the mechanism for dilating the vessel. The shaft of the delivery system is coaxial over the entire length of the catheter. The inner lumen of the coaxial catheter is designed to accommodate a maximum guidewire diameter of 0.035 inches. The outer lumen of the coaxial catheter is used for inflation and deflation of the balloon. The proximal end of the catheter contains a luer adapter with two ports; one port is used for accessing the guidewire lumen while the second port facilitates inflation and deflation of the balloon. The delivery catheter is offered in an 80 cm length. The Edwards Peripheral Dilatation Catheter products are supplied sterile and are "single-use only" devices.

9. Intended Use:

The Edwards Peripheral Dilatation Catheter is intended to:

- dilate stenoses in 10 – 14mm peripheral arteries,
- treat obstructive lesions of native or synthetic A-V fistulae and/or
- expand endoluminal stent graft elements in the aorta and iliac arteries

10. Technological Characteristics:

Comparisons of the new and predicate devices show that the technical characteristics such as materials, performance properties, biocompatibility, and packaging are identical or substantially equivalent.

11. Performance Data:

Edwards Lifesciences completed bench testing such as balloon burst strength, balloon compliance, balloon inflation/deflation, balloon fatigue, as well as tensile strength testing on applicable joints of the delivery system. The results indicate that the Edwards Peripheral Dilatation Catheter performed in a manner substantially equivalent to the predicate devices cited in item 7 above.

12. Conclusion:

Since the Edwards Peripheral Dilatation Catheter has similar intended use, design, materials, performance, safety, effectiveness and labeling, it may be considered substantially equivalent to the predicate devices cited in item 7 above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT - 2 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Edwards Lifesciences LLC
c/o Mr. Kevin Drisko
Senior Manager/Regulatory Affairs
One Edwards Way
Irvine, CA 92614

Re: K032587
Trade Name: Edwards Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 21, 2003
Received: August 22, 2003

Dear Mr. Drisko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

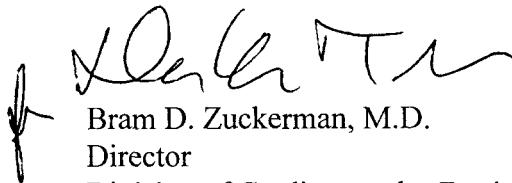
Page 2 – Mr. Kevin Drisko

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



510(k) Number (if known) _____

Device Name: Edwards Peripheral Dilatation Catheter

Indications for Use:

The Edwards Peripheral Dilatation Catheter is intended to:

- dilate stenoses in 10 – 14mm peripheral arteries,
- treat obstructive lesions of native or synthetic A-V fistulae and/or
- re-expand endoluminal stent graft elements in the aorta and iliac arteries

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K032587

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____